

REMARKS

Applicants confirm the provisional election without traverse of the invention of group II, claims 37-56 and 77-84.

Double Patenting

Claims 37-43, 55-58 and 77-84 were rejected on the grounds of double patenting. Of those claims, claims 37, 55, 77 and 82 are independent. These claims are amended in this Office Action such that they are patentably distinct from the identified corresponding claims in co-pending U.S. Patent Application Serial No. 09/886,074. Further, those corresponding claims in co-pending U.S. Patent Application Serial No. 09/886,074 have been amended as well.

The Examiner is handling both this patent application and U.S. Patent Application Serial No. 09/886,074, so that the Examiner can verify these changes to co-pending U.S. Patent Application Serial No. 09/886,074. Further, this Response to Office Action is filed on the same day as the Response to Office Action in U.S. Patent Application Serial No. 09/886,074 in order to facilitate examination of both. Due to the amendment of claims in this patent application and in co-pending U.S. Patent Application Serial No. 09/886,074, the claims are now patentably distinct, and withdrawal of the double patenting rejection of claims 37-43, 55-58 and 77-84 is respectfully requested.

35 U.S.C. §112

Claims 47, 48, 52, and 53 were rejected for utilizing the term "translatable." Those claims, as well as claims 39 and 40, have been amended to remove that term. However, Applicants do not acquiesce in the rejection of any claim based on use of the term "translatable," because that term is familiar to one of ordinary skill in the art, and appears in

both general-purpose and technical dictionaries. A patentee may be his own lexicographer, but is not required to be one.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 37-44

Amended claim 37 claims "[a]n anastomosis device applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising: a first tube configured to receive a unitary anastomosis device; a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another to deploy the anastomosis device, wherein said deployed anastomosis device has two spaced-apart flanges; and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out of the side of the tube.

In contrast, U.S. Pat. No. 6,024,748 to Manzo ("Manzo") neither discloses nor suggests every element of amended claim 37. Instead, Manzo discloses a plurality of individual clips rather than a "unitary anastomosis device." (*e.g.*, Figures 8-9; column 3, line 3; column 6, lines 12-15; column 9, lines 43-48; column 11, lines 13-16).

In addition, U.S. Pat. No. 5,833,698 to Hinchliffe et. al. ("Hinchliffe") neither discloses nor suggests every element of amended claim 37. Hinchliffe discloses an anastomosis device that has a ring-shaped body and a number of barbs extending from it. (*e.g.*, Figure 25; column 11, lines 12-14). However, Hinchliffe neither discloses nor suggests

a deployed anastomosis device having two spaced-apart flanges.

Thus, neither cited reference discloses nor suggests each and every element claimed in amended claim 37, and Applicants believe claim 37 is in condition for allowance. Claims 38-44 depend directly or indirectly from claim 37, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 45-49

Amended claim 45 claims “[a]n anastomosis applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising: a first tube configured to receive a unitary anastomosis device, wherein said device comprises a distal end and a proximal end and a longitudinal axis; a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another, configured for deployment of the anastomosis device, and configured to remain outside the graft vessel; and wherein the applicator has a pre-deployment configuration where at least one tube extends beyond the distal end of the device.”

In contrast, U.S. Pat. No. 5,976,178 to Goldsteen (“Goldsteen”) neither discloses nor suggests every element of amended claim 45. Instead, Goldsteen discloses a plurality of tubes configured for motion through the graft vessel. (e.g., Figures 18, 23, 24; column 14, lines 1-6).

The same discussion of Manzo applies here as applied in the discussion of claims 37-43 above.

Thus, neither cited reference discloses nor suggests each and every element claimed in amended claim 45, and Applicants believe claim 45 is in condition for allowance. Claims 46-49 depend directly or indirectly from claim 45, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 50-54

Amended claim 50 claims “[a]n anastomosis applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising a first tube configured to receive an anastomosis device; a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another, configured for deployment of the anastomosis device and configured to remain outside the graft vessel; a vessel penetrating member configured for incision of the target vessel; and wherein the applicator is configured to maintain contact with the target vessel from the time of incision through complete deployment of the anastomosis device.”

In contrast, U.S. Pat. No. 5,695,504 to Gifford (“Gifford”) neither discloses nor suggests every element of amended claim 50. Instead, Gifford discloses an applicator in which an anvil is inserted into the lumen of the target vessel through a pre-existing slit, such as formed “with a scalpel or other sharp instrument.” (*e.g.*, Figures 4, 5A; column 18, lines 60-64). Thus, the anvil of Gifford is not a vessel penetrating member, because it does not penetrate the tissue of the target vessel; rather, it simply passes into the lumen of the target vessel through an incision that has already been made with a separate tool.

The same discussion of Goldsteen applies here as applied in the discussion of claims 45-49 above.

Thus, neither cited reference discloses nor suggests each and every element claimed in amended claim 50, and Applicants believe claim 50 is in condition for allowance. Claims 51-54 depend directly or indirectly from claim 50, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 55-58

Amended claim 55 claims “[a]n anastomosis tool for use in connecting an end of a graft vessel to the side of a target vessel, the tool comprising a vessel penetrating member configured to penetrate the target vessel and configured for withdrawal outside the lumen of the graft vessel, wherein the tool is configured to penetrate the target vessel and deliver a one-piece anastomosis device to connect the graft vessel to the target vessel.”

In contrast, Goldsteen neither discloses nor suggests each and every element of amended claim 55. Instead, Goldsteen discloses a collapsible tip 412 configured for withdrawal through the lumen of the graft vessel. (*e.g.*, Figures 14, 15, 18, 23, 24; column 12, lines 27-28; column 14, lines 4-5). Indeed, the collapsible tip 412 is collapsible in order to allow it to be removed through the graft conduit after the anastomosis is complete; because “all or substantially all of the necessary apparatus is inserted into the patient via the patient’s existing body organ tubing” using a catheter 210, the tip is necessarily removed from the graft conduit. (*e.g.*, column 2, lines 41-43; column 12, line 66 through column 13, line 1).

Thus, Goldsteen neither discloses nor suggests each and every element claimed in amended claim 55, and Applicants believe claim 55 is in condition for allowance. Claims 56-58 depend directly or indirectly from claim 55, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 77-81

Amended claim 77 claims “[a] method of performing anastomosis between a graft vessel and a target vessel, the method comprising: receiving an anastomosis device on an anastomosis device applicator having a vessel penetrating member; connecting a graft vessel to the anastomosis device on the anastomosis device applicator; penetrating a target vessel with the vessel penetrating member of the anastomosis device applicator; advancing the

anastomosis device into the penetration in the target vessel; deploying the anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel; and maintaining the anastomosis device applicator outside of the lumen of the graft vessel during the receiving, connecting, penetrating, advancing and deploying.”

In contrast, Goldsteen neither discloses nor suggests every element of amended claim 77. Instead, Goldsteen discloses an applicator configured for placement within the graft conduit. (*e.g.*, Figures 15, 17, 18, 23, 24; column 14, lines 1-6).

The same discussion of Gifford applies here as applied in the discussion of claims 50-54 above.

Thus, neither of the cited references discloses nor suggests each and every element claimed in amended claim 77, and Applicants believe claim 77 is in condition for allowance. Claims 78-81 depend directly or indirectly from claim 77, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 82-84

Amended claim 82 claims “[a] method of performing anastomosis between a graft vessel and a target vessel, the method comprising: receiving a one-piece anastomosis device on an anastomosis device applicator including a first tube and a second tube substantially coaxial with the first tube; connecting a graft vessel to the anastomosis device on the anastomosis device applicator with an end of the graft vessel passing out a side hole of at least one of the first and second tubes; and deploying the anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel.”

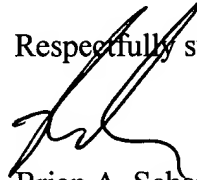
The same discussion of Manzo applies here as applied in the discussion of claims 37-43 above. Thus, Manzo neither discloses nor suggests each and every element claimed in amended claim 82, and Applicants believe claim 82 is in condition for allowance. Claims 83-

84 depend directly or indirectly from claim 45, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of pending claims 37-58 and 77-84 is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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